

REMARKS

In the final Office Action dated March 20, 2006, the United States Patent and Trademark Office (hereinafter "the Office") rejected Claims 1-5, 51, and 52 under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of U.S. Patent Application Publication No. 2002/0032582 (hereinafter "Feeney et al."), the teachings of U.S. Patent Application Publication No. 2002/0065683 (hereinafter "Pham et al."), and further in view of the teachings of U.S. Patent No. 4,971,362 (hereinafter "Lapsker"). Claims 6-8, 10, 53, and 55 were rejected under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of Pham et al. and further in view of the teachings of Feeney et al. Claims 9, 16-20, and 31-45 were rejected under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of Pham et al., Feeney et al., and Lapsker. Claims 21, 23-25, and 54 were rejected under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of Pham et al., Feeney et al., and further in view of the teachings of U.S. Patent No. 5,628,530 ("Thornton"). Claim 22 was rejected under 35 U.S.C. § 103(a) as being unpatentable in view of the teachings of Pham et al., Feeney et al., Thornton, and Lapsker.

The Office withdrew its reliance on Feeney et al., and Pham et al. as anticipatory references, hence conceding that there are defects connected with Feeney et al., and Pham et al. The Office withdrew its rejection under 35 U.S.C. § 101, hence conceding that the subject matter of all claims are statutory. Pham et al. has been overcome by the previously submitted affidavit and its exhibits as well as a newly submitted declaration and its exhibits under 37 C.F.R. § 1.131.

Prior to discussing in detail why applicants believe that all of the claims in this application are allowable, a brief description of applicants' invention and brief descriptions of the teachings of the cited and applied references are provided. The following discussions of the disclosed embodiments of applicants' invention and the teachings of the cited and applied

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESSTM
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

references are not provided to define the scope or interpretation of any of the claims of this application. Instead, such discussions are provided to help the Office better appreciate important claim distinctions discussed thereafter.

The Affidavit Under 37 C.F.R. §1.131.

The Examiner indicated that the affidavit filed on December 7, 2005, under 37 C.F.R. §1.131 is ineffective to overcome the Pham et al. reference because of two issues. First, where the conception occurs prior to the date of the reference, but reduction to practice this afterwards, the Office indicated that it is not enough merely to allege that the applicants had been diligent. The second issue is that the Office requires a showing of possession of the whole invention.

Applicants turn to the first issue. Because the previously filed affidavit includes statements and facts showing conception and reduction to practice before July 28, 2000, diligence is presumed. It is a complete mystery how the Office finds the lack of diligence in applicants' affidavit. The Office did not object to Paragraph 2 of the affidavit, which stated that one of ordinary skill in the software art can produce software prior to July 28, 2000. However, to be helpful to the Office, applicants submit herein a declaration under 37 C.F.R. §1.131 and its exhibits showing refinement of the software from July 27, 2000, to May 22, 2003. With this showing, applicants respectfully request withdrawal of the objection to the affidavit because of the issue of diligence.

Turning to the second issue, it is respectfully submitted that the Office has not stated the correct case law governing the use of 37 C.F.R. §1.131 affidavit to overcome a 35 U.S.C. § 103(a) rejection. Nevertheless, to advance the prosecution of this patent application, applicants would like to point out the following. First, the Office alleged that applicants have not shown where in the affidavit teachings and suggestions of ordering drug samples without the use of a

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS^{PLLC}
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

sales representative. The Office, on page 3 of the final Office Action, indicated that Feeney et al. fails to teach ordering drug samples without the use of a sales representative and that Pham et al. cures this defect of Feeney et al. by allowing physicians to order samples via the Internet.

Page 13 of Exhibit A of the previously filed affidavit shows that the architecture uses an "IIS 5.0 Web server," hence signifying conclusively of applicants' use of the Web for pharmaceutical sample disbursements. The Office indicated that page 4 of Exhibit A of the previously filed affidavit discusses in Section 1.2.4 that a pharmaceutical sales representative visits physicians to authorize release of additional vouchers. The previously filed affidavit and its exhibits show the use of the Web for a physician to order drug samples. If a prescriber can do this, there is no need to use a sales representative. However, it does not prevent a pharmaceutical company from using both the claimed invention and its sales representatives. In this particular case, various claimed inventions have disclaimed the use of the sales representatives. Additionally, Section 1.2.4 is under Section 1.2, which describes various user roles of the system. The claimed invention claims that which is connected with MedManage (the assignee of the claimed invention) and disclaims the use of sales representatives. It is worth reminding that the Examiner must take the affidavit at face value. The applicants need do no more than make a *prima facie* showing of prior inventions. See *ex parte McGuckin*, 202 U.S.P.Q. 398(c) (POBA 1975); and *In re Eickmeyer*, 602 Fed.2d 974, 202 U.S.P.Q. 655, 660, (C.C.P.A. 1979).

The Office additionally indicated that the applicants need to show where in the affidavit support for the brand rule limitation is recited in the claims. The Examiner in the final Office Action on page 23, indicates that brand rules "can be based on many factors, including the specialty of the prescriber," citing applicants' specification, at page 17, lines 20-22. The Office further indicated that Feeney et al. teaches at paragraph 0283 the use of physician practice for targeting promotions. Applicants point out on page 20 of Exhibit B of the previously filed

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS^{LLC}
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

affidavit the specialty of a physician is specified. Hence, applicants believe that the previously filed affidavit and its exhibits show possession of various issues raised by the office. Withdrawal of the objections to the previously filed affidavit and its exhibits and consideration of the newly submitted declaration and its exhibits is respectfully requested.

Background

Traditionally, a sales representative of a pharma visits one or more prescribers, leaves behind some samples of the drugs, and waits in trust that the prescribers will prescribe these drug samples to the patients. When a sales representative visits a prescriber, the sales representative is performing two actions. First, the sales representative educates the prescriber about the efficacy of the drug samples for various disease states and differentiates them from any competitive drugs in the marketplace. Second, the sales representative leaves drug samples behind with the prescriber so that he can dispense these drug samples to his patients. For each sales representative used by the pharma, the pharma incurs numerous expenses including purchasing and maintaining an automobile for the sales representative to travel to the prescribers, as well as paying a salary, benefits, and so on. Also a growing number of billions of dollars are spent each year on everything necessary to support the distribution of drug samples, such as delivery. When this cost is multiplied by the cost of employing multiple sales representatives, the pharma cannot afford to visit all prescribers to solicit patronage of its drugs.

Summary of the Claimed Invention

Applicants' claimed invention is directed to a system for promoting and distributing pharmaceutical drugs, a drug sample fulfillment platform, a networked system for ordering pharmaceutical sample drugs, and a method for accessing a drug sample fulfillment platform. The system for promoting pharmaceutical drugs comprises a computer-readable set of ground rules for guiding a distribution of drug samples of a drug to cause one prescriber's drug sample

availability and characteristics to be different from those of another prescriber. The system further comprises a computer-implementable drug sample fulfillment platform for implementing the set of ground rules to allow a prescriber to obtain drug samples to dispense to a patient without the use of a sales representative.

Applicants' claimed invention also includes a system for distributing pharmaceutical drugs which comprises a drug sample fulfillment platform for accessing drug sample services, and a first set of Web pages coupled to the drug sample fulfillment platform through which a prescriber can access the drug sample fulfillment platform to order drug samples if a set of brand rules which specify drug sample availability and characteristics for the prescriber permits the prescriber to access the drug sample fulfillment platform.

Applicants' claimed invention is further directed to a drug sample fulfillment platform, which comprises a drug sample Web site for mating with a portal that is selected from a group consisting of prescriber-oriented Web portals, an e-detailing service, a Web site regarding a drug brand, and an on-line physician learning site. The drug sample fulfillment platform further comprises a request database for receiving requests of a prescriber through the drug sample Web site for drug samples. The request database responds to the prescriber by allowing the prescriber to print coupons, or to print an order form for physical samples, or pass out pre-printed vouchers if a set of brand rules allow the prescriber to receive drug samples in the form of print coupons, order forms for physical samples, or pads of pre-printed vouchers.

Applicants' claimed invention yet further includes a networked system for ordering pharmaceutical sample drugs. The networked system includes a drug sample fulfillment platform that comprises a drug sample Web site for mating with a Web portal when a prescriber selects a hyperlink. The drug sample Web site presents the Web page including selectable

options for the prescriber to order drug samples, the time frame in which those drug samples are valid for the prescriber being specified by a set of brand rules.

Applicants' invention yet further includes a method for accessing a drug sample fulfillment platform. The method comprises activating a link to access the drug sample fulfillment platform from a Web portal. The method further comprises creating a transaction that includes a prescriber identifier and a partner identifier. The method also comprises mating a drug sample Web site to the Web portal, allowing a prescriber to navigate and order drug samples only for drugs specified by a set of brand rules which include physical samples, pre-printed vouchers, and print coupons.

Pham et al. Reference

Without admitting whether Pham et al. substantially shows or describes the claimed invention, applicants previously submitted an affidavit and its exhibits and now submit a declaration and its exhibits under 37 C.F.R. § 1.131 to overcome Pham et al. Consideration of the previously submitted affidavit and its exhibits, as well as the presently submitted declaration and its exhibits, and withdrawal of Pham et al. as a reference is respectfully requested.

Summary of Feeney et al.

Feeney et al. explains that, in light of the substantial amount spent by pharmaceutical companies in order to maintain sample programs, "it is of utmost importance for these companies to gain access to medical offices for purposes of physician detailing and sample program monitoring." In contrast, various embodiments of applicants' invention need not access medical offices but instead prescribers access a common drug sample fulfillment platform through a Web portal. Feeney et al. describes obtaining accurate knowledge of medical office sample inventory levels to enhance the efficiency of pharmaceutical representatives by allowing them to make

informed decisions regarding the appropriate timing of medical office visits and the necessary quantities of appropriate sample medications required for restocking. See paragraph 0015.

In order to gain access to medical offices, Feeney et al. designs a system that has three major components according to paragraphs 0191, 0178, and 0181: a front office server, a central server, and one or more dispensers. Note that various embodiments of applicants' invention need not invade the medical offices of prescribers by placing a front office server there to monitor the activities of prescribers. Feeney et al. specifies that the front office server and the dispensers are placed in the medical office of a physician and the central server can reside elsewhere. The reason Feeney et al. wants the front office server to be placed in a medical office is to gain access to the medical office for monitoring purposes. For example, paragraph 0191 describes that the front office server can have a database that includes the patient information, marketing content, drug interaction information. The front office server also include a radio frequency transceiver for controlling medication dispensers. See paragraph 0192.

The central server of Feeney et al. can be configured to receive and process the determination of whether the medication is appropriate for a patient. The central server can receive tracked sample medication user information. The system of Feeney et al. includes a Web site that is connected to the central server. The Web site is configured to provide controlled user access to system information. The system information can include a financial report, an inventory report, a user's report, a regulatory report, a sales report, an order management report, a business report, and the like. A typical user includes pharmaceutical representatives, who can access specific sampling reports by accessing the appropriate Web site through any Web browser.

The dispensers of Feeney et al. are controlled by the front office server and the central server to execute medication dispensing. A large number of physician offices, each having its

own front office server, communicate with a central server. Dispensing of medication can either occur automatically when a dispense command or control signal is received by the appropriate dispenser unit or manually when an authorized system user accesses the dispenser unit to physically remove the appropriate medication. The system of Feeney et al. is centered on its ability to control the dispensers so as to collect usage data from the activities of the physicians. Paragraph [0059] of Feeney et al. discusses that: "This method of data collection, processing and presentation greatly increases the work efficiency of pharmaceutical representatives and provides pharmaceutical companies with information that was rarely obtainable previously. " In contrast, applicants' claimed invention does not use and specifically disclaims the use of sales representative. Notwithstanding this contradistinction, the Office insists in the use Feeney et al. as a part of a combination of references.

Summary of Lapsker

The system of Lapsker is directed to a prescription pad that comprises the preprinted prescription leaf and preprinted check leaf. The preprinted prescription leaf bears a preprinted prescription for a distinct pharmaceutical product, as well as a zone for entry of patient information and a zone for entry of the signature of the prescribing physician. The check leaf bears on one face a preprinted check in favor of a dispensing pharmacist and has a value based on the value of the prescribed product and a dispensing fee and has an endorsing zone preprinted with a dispensing acknowledgment legend relating to the preprinted prescription with an entry portion for entry of the endorsing signature of the dispensing pharmacist. The check leaf is preferably coded to identify the physician. The prescription pad can be employed for the prescribing of free starter dosages of the pharmaceutical product for the patient or to provide the patient with a discount. The pharmacist is reimbursed simply by depositing the endorsed preprinted check in his bank account, and the control body on whose account the check is drawn

is able to monitor the use of the preprinted prescriptions by physicians and provide the pharmaceutical company with valuable information.

Summary of Thornton

The system of Thornton is directed to tracking demographics of physicians who prescribe starter drug samples dispensed to patients from different dispensing locations and employ a multipart product specific sample drug voucher, such as a smart card or a preprinted two part voucher. The two part voucher has a marketing information portion and a separable prescription portion to be completed by the prescribing physician with starter drug sample quantity and dosage information along with patient demographic information. The prescription portion is segregated from the marketing information portion at the pharmacy either electronically by a card reader (if it had been encoded on a smart card by the physician) or physically by separation along a perforation (if recorded on a two part voucher). Provided that such information is electronically and retrievably stored in a pharmacy computer, the tracking information is electronically transmitted to a central remote computer, such as at the drug manufacturer, for subsequent rapid market analysis.

The Claims Distinguished.

None of the cited and applied references teach "a computer-readable set of brand rules for guiding a distribution of drug samples of a drug to cause one prescriber's drug sample availability and characteristics to be different from those of another prescriber," as recited in Claim 1, among many other claim limitations. The Office has indicated that this limitation of Claim 1 is taught by Finney et al. at paragraphs 0283-0285. Paragraph 0283 discloses the following:

[0283] FIG. 20 illustrates one possible marketing distribution process. The central server 2002 can include the master marketing material content for

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS^{MLL}
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

all users or customers. The central server 2002 routes the marketing information to the front office servers of the users or customers 2004. The users and customers can include medical office system users and the like. The central server routes general or global marketing information as well as targeted or client practice specific marketing to the front office servers 2004 of the users. The front office servers can also include a patient/clinician decision engine in order to select and route appropriate marketing content to users. The decision engine can select and route marketing content based upon a prescribed medication, a disease state, physician practice, patient groups, and the like, for example. The decision engine process is discussed in more detail below in relation to FIG. 21 and FIG. 22.

There is nothing in paragraph 0283 that describes the recited limitation, which requires "a computer-readable set of brand rules for guiding a distribution of drug samples of a drug to cause one prescriber's drug sample availability and characteristics to be different from those of another prescriber." In paragraph 0283, Feeney et al. discusses the routing of "marketing information" from a central server to a front office server located in a medical office so as to allow Feeney et al. to monitor the activities of prescribers. No brand rules are discussed by Feeney et al. Applicants' claimed invention does not use a front office server, which is needed by Feeney et al., to decide marketing content to send to a physician. The claim limitation also requires both features of "availability and characteristics." That has not been shown by the Office. Because one or more claim limitations are entirely absent, no *prima facie* case of obviousness has been established by the Office.

Paragraph 0284 discloses the following:

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS^{PLC}
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

[0284] eCoupons can be pushed to the care provider at the time of dispensing the patient's product. For example, the marketing subsystem can provide for immediate eCoupon dispensing by maintaining a continuously updated database of specific eCoupon promotions on the central server. At the medical office, prior to each approval to dispense a medication, the front office server can communicate with the central server to determine appropriate eCoupons for retrieval. Upon retrieval, the front office server can either process the eCoupon electronically or provide a hard copy of the eCoupon at the time the medication is dispensed.

Paragraph 0284 of Feeney et al. has nothing to do with the recited limitation of Claim 1. Paragraph 0284 discusses that eCoupons can be pushed to a care provider at the time of dispensing a patient's product. The claimed invention does not work in this way and this portion of Feeney et al. has nothing to do with "a computer-readable set of brand rules for guiding a distribution of drug samples of a drug to cause one prescriber's drug sample availability and characteristics to be different from those of another prescriber." There is nothing in paragraph 0284 that talks about brand rules as required by the recited limitation. The Office explained on page 23 of the final Office Action that brand rules can be based on many factors, including the specialty of the prescriber, citing applicants' specification at page 17, lines 20-22. In the sentence just prior to the sentence cited by the Office in applicant's specification, it is explained that the brand rules are established on a prescriber-by-prescriber basis and are in effect when a prescriber requests drug samples. In the current situation, Feeney et al. explains at paragraph 0284 that eCoupons are pushed to the care provider at the time of dispensing the patient's product. Applicants' claimed invention does not push eCoupons to provider. But

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS^{MLC}
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

instead, it executes brand rules when a prescriber requests drug samples. This is not how the system of Feeney et al. works. It pushes eCoupons to the care provider at the time of dispensing the patient's product whereas applicants' claimed invention is not limited to the time of dispensing the patient's product. No *prima facie* case of obviousness has been established by the Office.

Paragraph 0285 discloses the following:

[0285] The following provides an example description of a targeted eCoupon delivery. The central server maintains a database of all market drug products for appropriate retailers and service providers. From their own list of products, each retailer and service provider chooses the products or services to be promoted and the duration of the promotion. Prior to the dispensing of a medication at any physician office, the central server receives a request to check the database for any appropriate eCoupons. In the search of its database, the central server might find several eCoupon matches, such as, a promotion for the specific medication being dispensed, a promotion for an OTC medication that ameliorates one of the side effects of the medication being dispensed, and a promotion for a disease management program that would likely benefit a patient taking the medication being dispensed.

There is also nothing in paragraph 0285 of Feeney et al. that teaches the recited limitation "a computer-readable set of brand rules for guiding a distribution of drug samples of a drug to cause one prescriber's drug sample availability and characteristics to be different from those of another prescriber." The system of Feeney et al. checks the database for eCoupons prior to dispensing of a medication. In the system of applicants, the act of providing drug samples is the

dispensation of the medication and the drug samples. Paragraph 0285 of Feeney et al. requires targeting eCoupon delivery just prior to dispensing of a medication at any physician office. No discussion pertaining to brand rules can be found in paragraph 0285. Thus, no *prima facie* case of obviousness has been established by the Office.

As a second example, none of the cited and applied references teach "a first set of Web pages coupled to the drug sample fulfillment platform through which a prescriber can access the drug sample fulfillment platform to order drug samples if a set of brand rules which specified drug sample availability and characteristics for the prescriber permits the prescriber to access the drug sample fulfillment platform," as recited in Claim 6, among other limitations. The Office has indicated that Feeney et al. teaches a system that discloses the claim limitation of paragraph 0283. To repeat for emphasis, the claim limitation requires, among many other things, the test "if a set of brand rules which specify drug sample availability and characteristics for the prescriber permits the prescriber to access the drug sample fulfillment platform." Feeney et al. does not work in this way. Paragraph 0284 of Feeney et al. discloses that eCoupons are made available to the care provider at the time of dispensing the patient's product. Nowhere in paragraphs 0283-0285 does Feeney et al. discuss the allowance a prescriber to access a drug sample fulfillment platform based on a set of brand rules which specify drug sample availability and characteristics for the prescriber. Thus, no *prima facie* case of obviousness has been established by the Office.

As a third example, none of the cited and applied references teach "a request database for receiving requests of a prescriber through the drug sample Web site for drug samples, the request database responding to the prescriber by allowing the prescriber to print coupons or to print an order form for physical samples or pads of pre-printed vouchers if a set of brand rules allow the prescriber to receive drug samples in the form of print coupons, order forms for physical

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS^{PLC}
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

samples, or pads of pre-printed vouchers," as recited in Claim 16, among other limitations. Nowhere do Feeney et al. and Lapsker teach or suggest, among many claim limitations, "if a set of brand rules allow the prescriber to receive drug samples in the form of . . . order forms for physical samples . . ." Feeney et al. teaches pushing eCoupons through a care provider whether or not the care provider requested them. Lapsker fails to teach "an order form for physical samples," among other limitations. Thus, the Office has failed to state the *prima facie* case of obviousness.

As a fourth example, none of the cited and applied references teach "a drug sample fulfillment platform that comprises a drug sample Web site for mating with a Web portal when a prescriber selects a hyperlink, the drug sample Web site presenting a Web page including selectable options for the prescriber to order drug samples, the time frame in which those drug samples are valid for the prescriber being specified by a set of brand rules," as recited in Claim 21, among other limitations. The Office indicated that Feeney et al. teaches in paragraph 0284 a system that determines the time frame in which drug samples are valid. That is not correct. Paragraph 0285 of Feeney et al. discusses that each retailer and service provider chooses the products or services to be promoted and the duration of the promotion. A duration of promotion is not the same as the time frame in which drug samples are valid for the prescriber as specified by a set of brand rules. The Office also indicated that Thornton discusses pre-printed vouchers with expiration date at Figure 4. That is also not correct. The recited limitation reads "the time frame in which those drug samples are valid for the prescriber being specified by a set of brand rules," among other limitations. There is no time frame in Figure 4 of Thornton. There is an explicit expiration date for the voucher of Thornton but no particular time frame. Additionally, the expiration date of Thornton is not connected to a prescriber. Thornton does show a blank line next to a field "prescriber's name," but Thornton does not specify a prescriber

connected with a time frame in which drug samples are valid. In essence, any prescriber that uses the voucher of Thornton would have the same expiration date and is not specific to any particular prescriber and is not specified by a set of brand rules. Thus, a *prima facie* case of obviousness has not been established by the Office.

As a fifth example, none of the cited and applied references teaches "mating a drug sample Web site to the Web portal allowing a prescriber to navigate and order drug samples only for drugs specified by a set of brand rules which include physical samples, pre-printed vouchers, and print coupons," as recited in Claim 31, among many other limitations. Feeney et al. as discussed at paragraph 0284 pushes eCoupons to care providers at the time of dispensing the patient's product. The claimed invention does not need to push drug samples to a prescriber at the time of dispensing the patient's product. Because of this unusual approach, the system of Feeney et al. has to ensure that any eCoupon "that is pushed" does not have a potential interaction with the medication that is being dispensed. See paragraph 0287.

Feeney et al. works in a way opposite from the system of Pham et al. Pham et al. does not have a front office server that works in the way required by Feeney et al. Moreover, Feeney et al.'s method of data collection, processing and presentation "greatly increases the work efficiency of pharmaceutical representatives." See paragraph [0059] of Feeney et al. In contrast, applicants' claimed invention does not use and specifically disclaims the use of a sales representative. Thus, a combination of Pham et al. and Feeney et al., which combination applicants specifically deny, would require the use of pharmaceutical representatives by Feeney et al. to be jettisoned or the technique of Pham et al. to be removed, and the resultant combination would be inoperative for either reference. As required by M.P.E.P. § 2143.01, the proposed modification cannot render the prior art unsatisfactory for its intended purpose. Because this is the case, there is no suggestion or motivation to make the proposed modification,

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS^{PLC}
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

citing *In re Gordon*, 733 Fed.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). Thus, the Office has failed to state a *prima facie* case of obviousness.

Because the Office has failed to state a *prima facie* case of obviousness, the rejections should be withdrawn. Independent Claims 1, 6, 16, 21, and 31 are clearly patentably distinguishable over the cited and applied references. Claims 2-5, 7-10, 17-20, 22-25, 32-45, and 51-55 are allowable because they depend from allowable independent claims and because of the additional limitations added by those claims. Consequently, reconsideration and allowance of Claims 1-10, 16-25, 31-45, and 51-55 is respectfully requested.

Respectfully submitted,

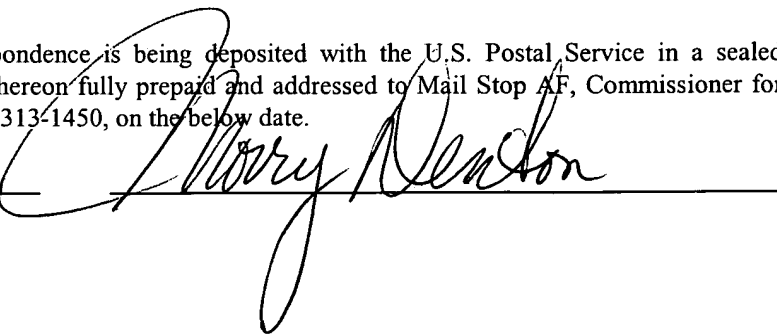
CHRISTENSEN O'CONNOR
JOHNSON KINDNESS^{PLLC}



D.C. Peter Chu
Registration No. 41,676
Direct Dial No. 206.695.1636

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CHRISTENSEN O'CONNOR JOHNSON KINDNESS^{PLLC}
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100